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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,287	05/30/2000	Yuhpyng L. Chen	U-014295-9	1655

7590

09/05/2003

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/05/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,287

Applicant(s)

CHEN, YUHPYNG L.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11,14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1-15 and 29-45 are pending.
2. Claims 1-15, and 30-45 are rejected.

Information Disclosure Statement

3. The information disclosure statements filed on April 14, 2003 and July 17, 2003 have been reviewed and considered, see enclosed copies of PTO FORMs 1449.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14, 15, and 30-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, claim 13 is directed to a pharmaceutical composition for the treatment of a "disorder or condition of which can be effected or facilitated by antagonizing CRF" as well as laundry list of disorders or conditions and claim 14 is also direct a laundry list of disorders or conditions that are not adequately described in the instant specification. There is insufficient descriptive

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support for the functional term of a "disorder or condition of which can be effected or facilitated by antagonizing CRF" as well as laundry list of disorders or conditions.

Moreover, the specification does not adequately describe what is meant by the functional characteristics of the of a "disorder or condition of which can be effected or facilitated by antagonizing CRF" as well as laundry list of disorders or conditions. The specification only has described the binding activities for compounds I, II and III as they are possessing CRF antagonist activity. There is no description of an actual reduction to practice, each step of the claimed pharmaceutical method with its intended use in order to show that the applicant was in possession of the claimed invention. Therefore, the claim fails to comply with the written description requirement.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 –13, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following explanations support these rejections. Under the variable section of B, the subvariable of R_2 in the group, "CHR₂NR₁R₂" should be changed to – R₂ --. Under the variable section of R₁, there are several blank spaces and letters that are underscored or underlined, for instance the group "C(O)(C₁-C₆_hydrocarbylene)(C₃-C₈ cyclohydrocarbyl)." In addition, under R₁ variable section, there is a number 1 that is currently listed in the group, "C₃-C₈ 1 cyclohydrocarbyl". In the section that defines the variable of "R₂" of claim 1 it is unclear as to what the I' represents for the group, S⁺(C₁-C₆ alkyl)(C₁-C₂ alkyl)I'. In addition,

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Under the variable section for R₁, the group, "S⁺(C₁-C₆ hydrocarbyl)(C₁-C₂ hydrocarbyl)" seems to be electronically unbalanced because its counter anion is missing, such as iodide, I⁻. The word --groups-- is misspelled as "grouips" under the variable of "R₂" of claim 1. Under variable section R₅, there is no comma between groups "nitro" and "halo". The variable of R₅ is underlined. The variable of R₁₅ from the formula of claim 1 is not defined. In addition, the variable of R₁₇ is not listed in the formula of claim 1; however, this variable of R₁₇ is defined. These anomalies render the claims vague and indefinite.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-15 and 30-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen of WO 94/13676. Chen teaches of the pyrrolopyrimidine compounds as depicted by formula (I), (see claim 1). In addition, Chen et al. teach that

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these compounds possess corticotropin-releasing factor antagonist activity, (see page 1, lines 6-8). These compounds have an identical core structure and identical substituents on the core ring structure. In addition, the physiological activities are analogous. The claims differ from the prior art by having a double bond in lieu of a single bond of a pyrrolidinyl ring moiety of the prior art. One having ordinary skill in the art would have been motivated to select the claimed compound with the expectation that substitution of a double bond for a single bond that is apart of pyrrolidinyl ring would not significantly alter the analogous properties of the compound of the reference due to the close structural similarity of the compounds.

11. Claims 1-13 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3,145,287. DE 3,145,287 teaches of the pyrrolopyrimidine compounds as depicted by formula (I), (see abstract and claims 1-10). These compounds have an identical core structure and identical substituents on the core ring structure. The claims differ from the prior art by having a double bond in lieu of a single bond of a pyrrolidinyl ring moiety of the prior art. One having ordinary skill in the art would have been motivated to select the claimed compound with the expectation that substitution of a double bond for a single bond that is apart of pyrrolidinyl ring would not significantly alter the analogous properties of the compound of the reference due to the close structural similarity of the compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones, whose telephone number is (703) 308-

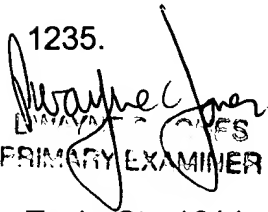
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4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


WAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
September 2, 2003